MINUTES FROM THE EPA SCIENCE ADVISORY BOARD
Drinking Water Committee
Telephone Conference Meeting
September 25-26, 2001

PURPOSE: The Drinking Water Committee (DWC) of the EPA Science Advisory Board (SAB) met via telephone conference on September 25 and 26, 2001 to plan for panel development and review of certain elements of EPA's analyses supporting the development of their proposed National Primary Drinking Water Standards for the Stage 2 Disinfection/Disinfectant Byproduct Rule and the Long Term 2 Enhanced Surface Water Treatment Rule. Attachment A is the Federal Register notice announcing the meeting (FR Vol. 66, No. 145, Page 39163, July 27, 2001). The meeting format was changed to a telephone conference format as a result of national emergencies which occurred on September 11, 2001. A note informing all who have contacted the SAB office about DWC activities in the past of the change in meeting format is in Attachment B. An agenda is included as Attachment C.

LOCATION: The meeting was coordinated from room 6013 Ariel Rios Building, US EPA, 1200 Pennsylvania Ave., NW, Washington, DC.

PARTICIPANTS: The following participated in this meeting: Drs. Rhodes Trussell, David Baker, Richard Bull, Mary Davis, Ricardo DeLeon, John Evans, Sidney Green, Barbara Harper, LD McMullen, Christine Moe, and Philip Singer. A committee roster is included as Attachment D. EPA Staff and persons from the public who participated in or observed the meeting are indicated on the log sheets (Attachment E).

MEETING SUMMARY: A summary of the Committee's activities follows.

1. Welcome and Introductory Remarks; Dr. Rhodes Trussell, Chair, (3:30 pm)

Members and public observers were logged into the call and Dr. Trussell called the meeting to order and welcomed the participants. He noted the purpose of the meeting and asked the DWC members to note for the record their affiliations and any connection to the items on the agenda.

Mr. Miller, DFO, stated that it is the SAB's standard practice to ask all members to introduce themselves and note their affiliations. Members are also encouraged to note any past links to the issues to be discussed in the telephone calls today and tomorrow (research, analysis, employer, etc.) so that all who participate in or observe the process will know this information. Mr. Miller noted that the meeting, due to its planning nature, did not have a concern for conflict of interest because the Committee will not be deliberating on the issues and providing advice to EPA in the form of responses to the charge.

Members participating are noted in the "Participants" section above. Comments made by specific members were as follows:

Name	Comment
Dr. Rhodes Trussell	Employed by Montgomery-Watson
Dr. David Baker	Retired Director of the Heidelberg College Water Quality Lab
Dr. Richard Bull	Half-time at Washington State University and Half time in his own consulting firm; has conducted DBP research; has made public statements on DBPs
Dr. Mary Davis	West Virginia University Dept. of Physiology and Pharmacology; has conducted DBP research in the past; has only made public statements in scientific meetings
Dr. Ricardo DeLeon	Metropolitan Water District, Water Quality Division; does research on methods that are relevant to the LT2 issue.
Dr. John Evans	Harvard University Center for Risk Analysis; has done risk assessments for chloroform several years ago.
Dr. Sidney Green	Howard University, part time; consulting part time. No involvement with DBPs in the past.
Dr. Barbara Harper	Half-time for the Yakima Indian Nation, half-time for as a consultant; no direct involvement with DBPs
Dr. L.D. McMullen	CEO for a public water utility in Des Moines, IA; is subject to regulations on drinking water.
Dr. Christine Moe	Emory University, International Health Program; some epidemiology experience but not on DBPs.
Dr. Philip Singer	Has done research on DBP formation and control; some consulting for utilities, engineering firms, AWWA, technical workgroups; some involvement with the MDBP stakeholder process.

2. Introductory Remarks by EPA on the Stage 2 Disinfection/Disinfectant Byproduct Rule Making Proposals, Dr. Stig Regli, OW, (3:45 pm - 4:15 pm)

Dr. Stig Regli, Office of Groundwater and Drinking Water, presented an overview of the Stage 2 Disinfection/Disinfectants Byproducts proposal (See Attachment F for his slides). Important points made by Dr. Regli included:

a) the Stage 1 D/DBP standards (promulgated in 1998) were developed via both stakeholder and regulatory negotiation procedures;

b) the Stage 2 M-DBP Rule Advisory Committee, convened in 1999 agreed on the contents of the proposed rule (phased MCLs based on a locational running annual average - LRAA- Stage 2A TTHM/HAA5 = 120/100 ppb LRAA plus 80/60 RAA (stage 1 compliance); and Stage 2B 80/60 ppb LRAA

c) the basis for the recommendations was concern for DBP health risks (especially reproductive/developmental effects), the probability that can still have high levels and detect the highest level sites in the distribution system even with Stage 1 in place, and the need to balance DBP and microbial risks.

Dr. Regli noted that the charge to the SAB reflects EPA's desire to ensure that the most cost effective monitoring strategies have been identified and the possibility of learning of additional opportunities for improvement from the SAB. The S2DBPR charge asks:

a) Charge Question 1: Given the current knowledge of DBP occurrence and the available health effects data, do the proposed locational running annual average (LRAA) standards, in conjunction with the initial distribution system evaluation (IDSE), more effectively achieve public health protection than the current running annual average (RAA) standards?

b) Charge Question 2: Is the IDSE capable of identifying new compliance monitoring points that target high DBP levels and is it the most appropriate tool available to achieve this objective?

Dr. Regli discussed the materials sent to the SAB by charge question (See Attachment G for the S2DDBPR background information).

Charge 1:

a) **Health risk** is not emphasized for SAB review because of the large uncertainties in the data. Further, the Stage 2 MCLs are not based on achieving particular risk goals. EPA is interested in knowing whether the SAB agrees that health effects information provided by the Agency is sufficient to support a health concern (mostly reproductive and developmental effects).

b) **Occurrence and Estimates of Reduction** information indicates DBP occurrence characteristics and by implication, limitations to Stage 1 as well as to indicate the extent to which Stage 2 might address Stage 1 limitations (further reduction in peaks). The data analyses indicate the bases for the Stage 2 LRAA:

i) systems meeting the RAA of 80/60 TTHM/HAA5 will still have some LRAA and individual measurements much higher than 80 or 60;
ii) highest TTHM measurements do not always correspond to high HAA5 levels (both must be measured to identify peaks);
iii) highest TTHM or HAA5 levels often occur at distribution system sites not representing maximum residence times (stage 1 sites may not capture peaks, basis for IDSE);

The agency is interested in knowing how well its analysis reflects the basis for these conclusions?

Further, the extent of peak reductions associated with Stage 2, the Agency would like to know if the SAB believes:

i) if the EPA's analysis is sound?
ii) if EPA is correctly estimating the percent reduction of peaks?
iii) if there are other approaches EPA should consider in characterizing reduction in peaks?

Charge 2:

a) Initial Distribution System Evaluation (IDSE):

The IDSE materials are intended to show:

i) how the IDSE applies to all drinking water utilities;
ii) the basis for the IDSE; and
iii) indicate processes by which systems would identify sites with highest DBP levels.

The IDSE provisions include: one year's monitoring on a regular schedule at sites throughout the distribution system during peak historical months for TTHM levels or water temperature; taking paired samples for HAA and TTHM analysis; system specific study to be based on other monitoring studies or data; and waivers for systems serving < 500 if monitoring sites for Stage 1 is sufficient for both highest HAA5 and TTHM. Dr. Regli provided an overview of the *IDSE Guidance Manual* for the Committee.

EPA would like to know in regard to the IDSE and the Guidance Manual:

i) if the IDSE is an effective approach for identifying sites with peak DBPs
ii) if the IDSE GM presents an effective strategy for selecting sites likely to have the highest peaks, and
iii) how might the GM be improved to achieve the above objective?

3. Committee Discussion and Planning for the Review of the Stage 2 DBP Technical Issues, Committee (4:15 - 4:55 pm)

DWC members made the following comments in regard to the presentation and the background materials:

a) Clarifications:

i) Other Toxic Endpoints: Dr. Green asked if endpoints other than reproductive and developmental effects had been considered for DBPs or if the focus was on reproductive/development because they drive decision making for this issue. OW representatives noted that the focus in Stage 2 was reproductive/developmental and peak exposure issues. However, carcinogenicity was a focus in Stage 1. They also noted that there is a high degree of uncertainty in information on all endpoints that make quantification of risk for each difficult. For Stage 2 and the

SAB, the question is has EPA's analyses (Reif, Tyl, etc.) demonstrated a "health concern" that needs to be addressed.

ii) Focus on TTHMs/HAA5 as "Indicators": Dr. Bull agreed that epidemiology studies reflect a reasonable level of confidence that bladder cancer is a concern in drinking water due to DBPs. He noted that it is not clear that the link to TTHM/HAA5 is well-demonstrated in the science data available. The point being that we may be looking under the "lamp post" to focus on these and missing other contaminants that are the actual causes.

OW representatives noted that the Stakeholder group had struggled with this issue as well and opted for a modest, somewhat simplistic proposal that is believed to give significant risk reduction from all contaminants, not just the indicators TTHM/HAA5 and still be able to be implemented at reasonable cost. The group believes that the risk will reduce for other contaminants in nearly the same proportions as it will for TTHM/HAA5 (Dr. Singer stated that this assertion was not born out by available studies). OW representatives also did not expect research to have all the answers to this issue any time soon. DWC members noted that making this transparent in the support documents is important so we do not mislead people.

iii) Criteria for Determining a "Health Concern": Dr. Evans noted that the terminology "enough concern to justify" is difficult to assess when there is not systematic approach reflected in the documentation that can be scrutinized to see how the determination was made. We are in essence applying the "precautionary principle" without explaining at what point "concern" is invoked.

iv) Initial Distribution System Evaluation: Dr. Singer noted that the document focuses on identifying "sites" (locations, spatial dimension) where one expects to find the highest DBP levels. There is no indication that "time" is also an important variable in DBP formation. DBP levels are also a function of residence time at a given location. Both "time" and "space" are important variables and need to be reflected in the analysis. Dr. Harper asked for clarification about the extent of time one expects to exist through. Dr. Davis noted that even with the number of samples that will be done, the number is still low and finding the locations with the highest level is often missed. It will be important to mandate that different sites will need to be considered over time so we have some assurance that we are monitoring at the "high" locations. Dr. Singer noted that, in reality, the rule actually focuses on "chronic exposures" but that it does so in a way that coincidentally may lower peak exposures as well.

OW representatives noted that the decision to go with averages reflected cost implications of not allowing any excursions above 80/60. The Stakeholder group recognized that there will still be excursions above the MCL, but believe that with the Stage 2 approach there will not be as many as with Stage 1. Sanitary surveys

and cyclic regulatory reevaluations will allow EPA and the systems to reevaluate the appropriateness of monitoring locations periodically.

b) Charge

After a short discussion, the Committee agreed that the charge as written in a broad manner is acceptable. A broad configuration will permit the review Panel to focus on a number of dimensions that it believes to be important.

c) Expertise Needs

Expertise needs discussed by the Committee included:

i) distribution system monitoring
ii) epidemiology
iii) those who could help with defining the "health concern" criterion

There is a strong need for augmenting the DWC with a person, or persons, having expertise in the implementation of distribution system monitoring. Epidemiology may be covered in the new DWC membership for FY 02, even so, additional epidemiologists will likely conclude similarly to Dr. Reif has in the analysis done for EPA. The uncertainty will not be removed by additional review. Help with defining the "health concern" criterion was not considered to be sufficiently important to add expertise in that area.

NOTE: Subsequent to the meeting, email suggesting the following candidates were received on 9/26/01 phone call:

i) Walter Grayman (Singer)
ii) Lew Rossman (Singer--EPA, not eligible for the panel but could be a resource person)
iii) Paul Boulos? (Singer)
iv) Andy Wilzcak, East Bay Municipal Utility District (Trussell)

4. Closing Remarks, Dr. Rhodes Trussell, Chair, DWC (4:55 - 4:59 pm)

5. Adjourn for the Day (5:00 pm)

Wednesday, September 26, 2001

1. Reconvene the Meeting, Dr. Rhodes Trussell, Chair, DWC (12:00 - 12:10 pm)

Dr. Trussell called the meeting to order and noted the business for the day. The meeting was to allow the DWC to complete its planning efforts for review of the two rules (clarifications, need for additional expertise, agree on the charge, make assignments to review groups, and set a date

for the face-to-face meeting).

The following DWC members reported into the call: Drs. Trussell, Green, Davis, Singer, Harper, Baker, McMullen, Evans, Bull, and Moe. EPA participants included: Dan Schmelling, Stig Regli, Mr. Mesner, Phil Burger, Susan Shaw, Cacey Parish, Jini Mohanty, Christa Rogers, and Trish Hall. Members from the public included: Curtis Amore (Cadmus), Dan Askineizer (Montgomery-Watson), Steve Via (AWWA), and Jeff Mosher (AMWA).

2. Introductory Remarks by EPA on the Long Term 2 Enhanced Surface Water Treatment Rule Making Proposal, Dr. Dan Schmelling, OW (12:10 - 12:40 pm)

Dr. Dan Schmelling presented an overview of the LT2ESWTR proposal for the Committee (see Attachment H for his slides and Attachment I for the background information provided to the DWC on the proposal). Important points made by Dr. Schmelling included:

a) The LT2ESWT rule:

i) will apply to all surface water system,
ii) address microbial pathogens with a focus on *Cryptosporidium* (hereafter "*C. parvum* or Crypto"),
iii) augment existing regulations,
iv) incorporate new data on occurrence, infectivity, and treatment, and
v) involve "risk balancing" relative to the Stage 2 DBP rule.

b) Advisory Committee Recommendations

The advisory committee of Stakeholders that met from 1999 through 2000 recommended that the LT2 take a site specific approach to addressing systems with highest vulnerability to *C. parvum* health concerns. This involves:

i) classifying the systems into "bins" based on their monitoring results from a 24-month monitoring program (large systems) and specifying treatment requirements based upon this classification;
ii) developing a "toolbox" of treatment options to comply with the treatment requirements; and
iii) having additional requirements for unfiltered systems and uncovered finished water reservoirs.

c) Specific Proposed Agency Requirements:

i) Source water monitoring for Crypto, *E. coli*, and turbidity (large systems 24 months; small systems *E. coli* only for 12 months with *C. parvum* monitoring depending on those results)
ii) classify into 'bins' based on *C. parvum* levels (see iii.aa. Below)

iii) treatment:

aa) Filtered systems: log-inactivations vary with 'bin" classification

BIN	Mean *C. parvum* Level	Additional Treatment Required
1	< 0.075oocysts/Liter	No action
2	0.075 - 1.0/L	1-log
3	1.0 - 3.0/L	2.0 logs (with 1-log disinfection)
4	≥ 3/L)	2.5 logs (with 1-log disinfection)

bb) Unfiltered systems: 2-log *C. parvum* inactivation (3-log if > 1/100L) and must use 2 disinfectants to inactivate;

cc) Cover or treat uncovered finished water reservoirs

dd) Disinfection bench marking (addresses need to ensure that microbial control is not overly reduced as a result of DBP concerns in the S2DBP rule)

iv) Microbial Toolbox: Tools Committee is being asked to review options including (some of the options receive prescribed log credits if used):

aa)Watershed control
bb) Alternative source/intake management
cc) Pretreatment (off-stream storage, pre-sedimentation, bank filtration)
dd) Improved Treatment (lower effluent turbidity, bag/cartridge filters, membranes)
ee) Disinfection (chlorine dioxide, ozone, UV); and
ff) Peer Review or Other Demonstration of Performance.

d) The charge to the SAB: The charge to the SAB involves three issues: statistical methods used in *C. parvum* occurrence estimates, pre-and post-regulation *C. parvum* risk analyses, and the treatment credits assigned to toolbox options.

i) Question 1: *C. parvum* Occurrence: Comment on the method used by EPA to estimate the national *Crypto* occurrence distribution.

aa) Risk and cost estimates reflect the national distribution of mean oocyst source-water levels estimated by EPA. Complex statistical methods were required to develop the occurrence distribution and EPA would like an independent review of their method.

bb) Important limitations on *C. parvum* occurrence data exist that prevent it from being used directly to develop national occurrence levels. Most are associated with the analytical method used for this living organism.

cc) Data analysis reflected recommendations from an expert workshop on statistical analysis of Information Collection Rule data (11/98).

dd) EPA developed a sophisticated hierarchical statistical model to develop its national occurrence distribution for Crypto. Statistical treatment in the model is Bayesian with diffuse priors. It employs Markov Chain Monte Carlo with Bayesian Inference Using Gibbs Sampling (BUGS).

ii) <u>Question 2: *C. parvum* Risk Assessment:</u> Comment on the Risk assessment for cryptosporidiosis, both prior to and following LT2ESWTR implementation.

aa) The Risk Assessment is key to determining benefits from the rule.

bb) The Risk Assessment involves estimating a number of highly variable and uncertain parameters (source water occurrence, treatment efficacy, infectivity of oocysts, fraction of infectious oocysts, daily volume of tap water ingested, morbidity/mortality). Note: Bayesian analysis was used in both the occurrence estimation model and in determining Crypto (*C. parvum*) infectivity.

cc) The Agency conducted an assessment of uncertainty and variability in the risk analysis using Monte Carlo techniques.

iii) <u>Question 3: Toolbox and Treatment Credits:</u> Comment on the treatment credits and design/implementation criteria for [certain of the] microbial toolbox options.

aa) The stakeholders recommended treatment credits for options based on proper design/implementation, but it did not recommend those design/ implementation conditions.

bb) EPA would like SAB's evaluation of whether the credits assigned and the design/implementation criteria are appropriate and supported by available data.

cc) EPA has asked SAB to focus on four of the toolbox options (those involving presumptive credits and where data compilation/analysis was relatively complete – Raw Water off-stream storage, Pre-sedimentation with coagulation, Lime softening, and Lower finished water turbidity).

3. Committee Discussion and Planning for the Review of the LT2ESWTR Proposal, Committee, (12:40 - 1:30 pm)

DWC members made the following comments in regard to the presentation and the background materials:

a) Clarifications

i) Statistics Workshop: Dr. Singer asked EPA to provide the members with a copy of the Statistics Experts Workshop report form 1998 – EPA agreed.

ii) Infectivity: Dr. Bull asked if the Crypto (*C. parvum*) isolates were from patients or animals and noted this needs to be clarified because if from patients they are likely selected for their ability to infect humans. Dr. Moe noted that different experts will disagree on infectivity questions because the uncertainty is still high on this issue.

iii) Toolbox Options: Dr. McMullen asked why the SAB was only requested to look at four of the options. OW representatives noted that these are the ones that are implemented on the basis of greater judgement than other options which are more measurement driven in their use. The others are open for comment if the DWC wishes to do so. Dr. Trussell asked about the peer review and demonstration of performance option under the Toolbox options. If we do not look at disinfection in the toolbox, how are we to comment on the "balance" (risk-risk) issue between S2DBP and LT2ESWT? Dr. Trussell noted that the charge does not ask us to comment on that issue.

iv) Occurrence Distribution: Dr. Bull wondered if the critical issue for the whole review is the method and results for deriving the Crypto (*C. parvum*) occurrence distribution. OW representatives noted this was important but other issues were also important. Members asked how the ICR and ICRSS results were combined in the estimates. OW Representatives noted that they are kept separate and estimates are generated based on each. Dr. Trussell also questioned why the expert group of statisticians recommended to ignore the extremes since these are where your illnesses come from.

v) Uncertainty analysis: Dr. Evans asked which bin classification seems to be the biggest driver of uncertainty in the analysis. OW representatives replied that occurrence seems to be the biggest driver itself. It does not appear to be associated with any specific bin.

b) Assignments

The following subgroups were identified for the DWC to use in preparing for the review:

i) S2DBPR:

aa) Subgroup on Health Protectiveness from LRAA/IDSE
- Dr. Mary Davis (Chair)
- Dr. Sidney Green
- Dr. Yvonne Dragan (if available)
- Dr. Barbara Harper
- Dr. Richard Bull

bb) Subgroup on IDSE Effectiveness and Appropriateness
- Dr. Phil Singer (Chair)
- Dr. David Baker
- Dr. LD McMullen
- Additional Expertise in Distribution Systems Monitoring

ii) LT2ESWTR

aa) Subgroup on Toolbox Effectiveness and Credits
- Dr. LD McMullen (Chair)
- Dr. Phil Singer
- Dr. Rhodes Trussell

bb) Subgroup on Microbial Risk Assessment
- Dr. Christine Moe (Chair)
- Dr. Rick DeLeon
- Dr. Gary Toranzos
- Additional microbial risk assessment expertise if Dr. Toranzos is unable to participate

cc) Subgroup on Risk Assessment Techniques
- Dr. John Evans (Chair)
- Dr. Christine Moe
- Additional risk assessment expertise in the area of uncertainty in the occurrence area

dd) Subgroup on Bayesian Statistics in EPA's modeling Effort Crypto (*C. parvum*) occurrence and Dose-response of Crypto Isolates
- Dr. John Evans (Chair)
- Dr. Rhodes Trussell
- Additional Bayesian statistics expertise (strong outsider)

c) Expertise Needs

The Committee will explore adding expertise in a number of areas:

i) Additional Expertise in Distribution Systems Monitoring especially in terms of identification of peak levels
ii) Additional microbial risk assessment expertise if Toranzos is unable to participate
iii) Additional risk assessment expertise in the area of uncertainty in the occurrence area
iv) Additional Bayesian statistics expertise (Drs. Trussell, Moe, Evans and Tom Miller will meet via telephone conference during the week of October 1-5 to discuss this need).
v) Epidemiology

The public comment period for nominating candidates for the review will close on October 12, 2001. We should select the final panel from among our own, EPA's, and the public recommendations before October is out.

d) Meeting Date

The DWC agreed to meet to conduct the two reviews from December 10 - 12, 2001. The 12th will be a half-day meeting. The likely location will be Irvine, CA. A site will need to be located.

4. Adjourn the Meeting

The Chair adjourned the meeting at 1:50 pm.

I certify that these minutes are accurate to the best of my knowledge.

/ S /

Dr. Rhodes Trussell
Chair
EPA SAB Drinking Water Committee

/ S /

Mr. Thomas O. Miller
Designated Federal Officer
EPA SAB Drinking Water Committee

Attachments

A FR 66(168), pp. 45676-45677, 8/29/01
B Drinking Water Committee Meeting Change, (note to interested parties from T Miller, 9/18/01)
C Agenda
D DWC Roster
E Log-in Sheets
F S2DBPR briefing charts, Stig Regli, 9/25/01
G S2DBPR background information (filed in the FACA file in Part 6)
H LT2ESWTR briefing charts, Dan Schmelling, 9/26/01
I LT2ESWTR background information (filed in the FACA file in Part 6)